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EXAMINER

BUI, VY Q

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/864,389

Applicant(s)

PINCHASIK ET AL

Examiner

Vy Q. Bui

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 31-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 42-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 31-41 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Drawings***

Figure 8 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: section "Brief Description of The Drawings" describes incorrectly Fig. 8 as "an enlarged view of one cell used in the pattern of Fig. 7.

Appropriate correction is required.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: the recitation "a third loop containing section the third loop containing section," (line 8, claim 1) is not grammatical proper. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

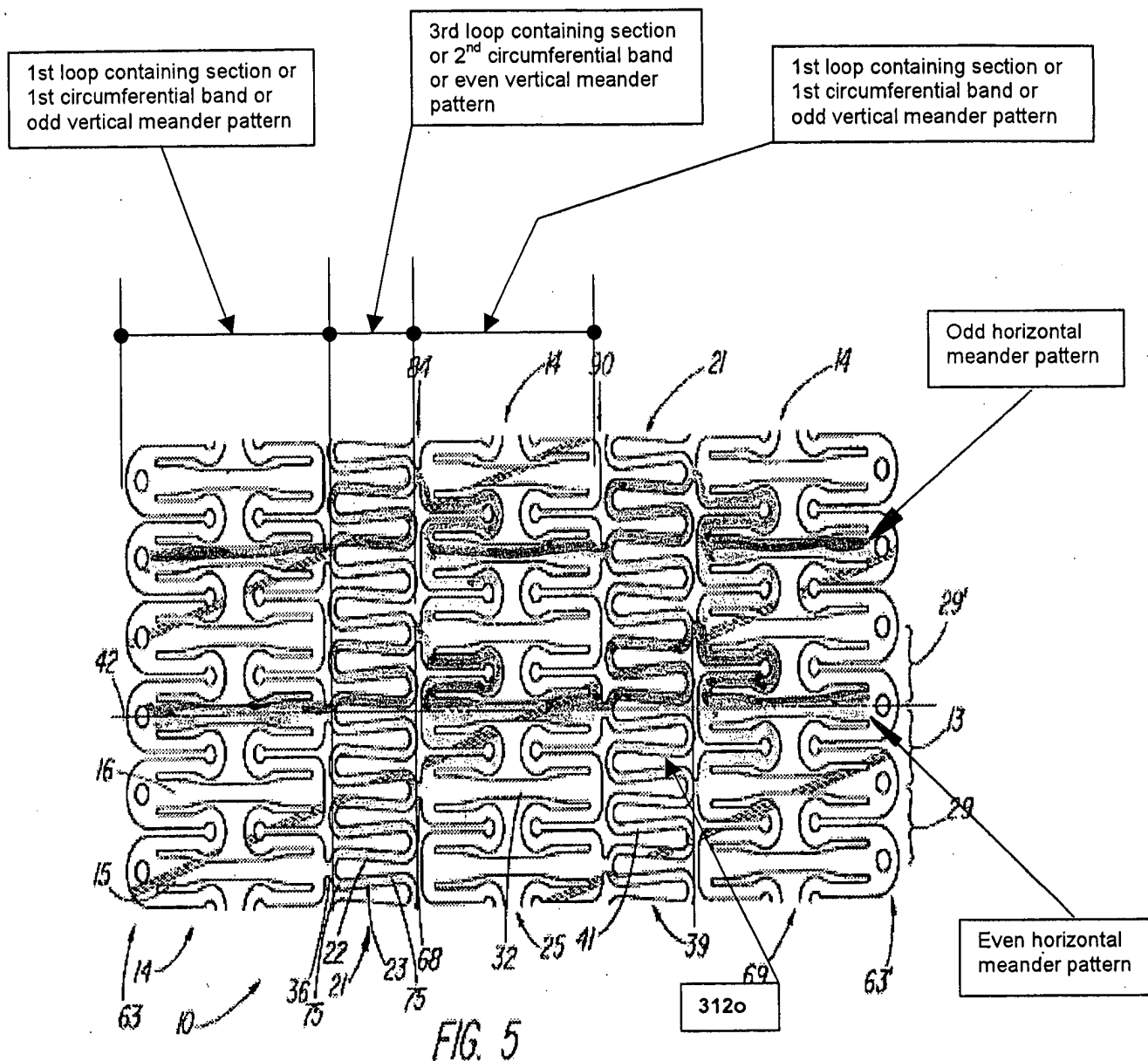
The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

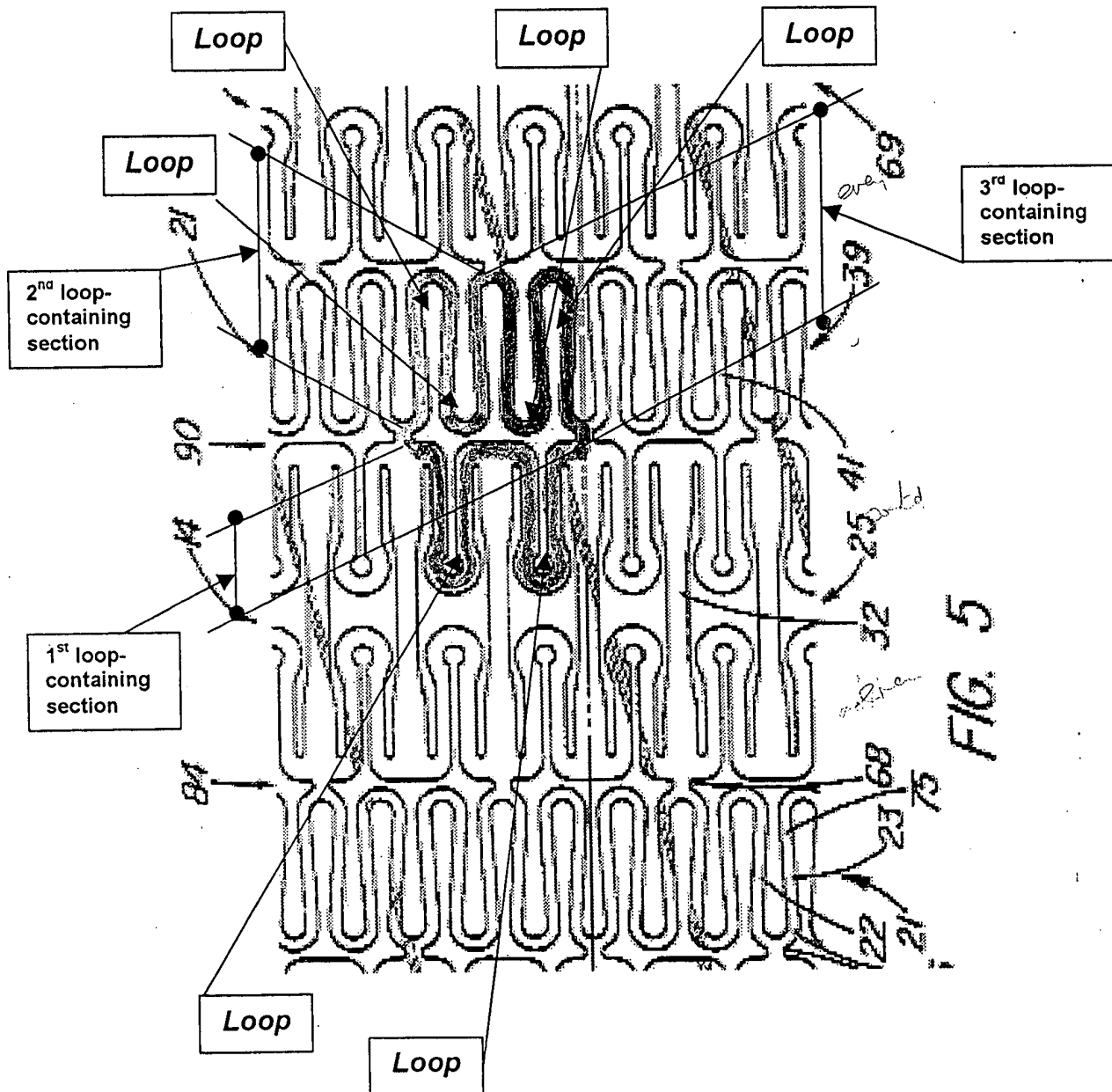
Claim 1 recites the limitation "the circumferential direction" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the cell's" in line 15. There is insufficient antecedent basis for this limitation in the claim.

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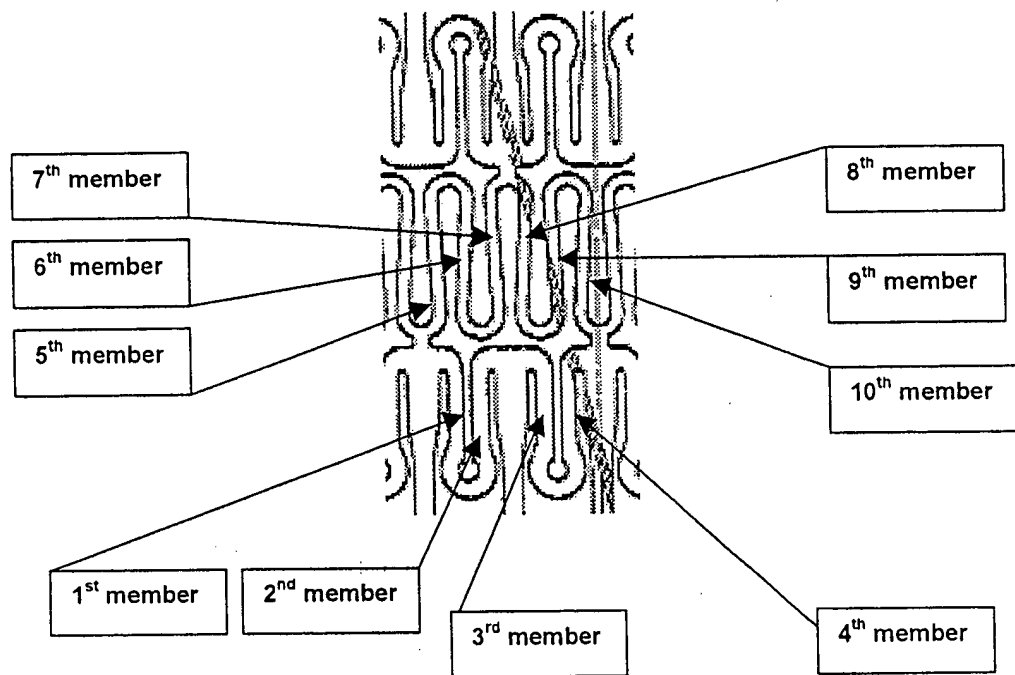


FIG. 1

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1, 2, 4, 6, 7, 9, 11-12, 14, 16-17, 19, 21-22, 24, 26-27, 29, and 42-44 are rejected under 35 U.S.C. 102(e) as anticipated by BERRY et al (6,231,598).

As to claims 1 and 6, BERRY (Fig. 5, also Fig. 1, this paper) discloses a stent having first loop containing sections/first circumferential bands of loops at a first frequency, second loop containing sections/first circumferential bands of loops of said first frequency, and third loop containing sections/second circumferential bands of loops of a second frequency disposed between the first and second loop containing sections. The second frequency is higher than the first frequency. The first or second loop containing sections/the first circumferential bands and the third loop containing sections/the second circumferential bands define cells (yellow color, Fig. 5 and Fig. 1, this paper). Notice that because the 5<sup>th</sup>, 6<sup>th</sup>, 7<sup>th</sup>, 8<sup>th</sup>, 9<sup>th</sup> and 10<sup>th</sup> members shown in Fig. 1 of the third loop containing sections/second circumferential bands are more flexible than the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> members, the 5<sup>th</sup>, 6<sup>th</sup>, 7<sup>th</sup>, 8<sup>th</sup>, 9<sup>th</sup> and 10<sup>th</sup> members of the third loop containing sections/second circumferential bands of the second (higher) frequency contribute most of the stent cells' elongation or shortening, and therefore contribute most of the deformation during flexing of the stent.

As to claim 42, BERRY (Fig. 1 and 5, this paper) shows the loops in the first and second loop containing sections are 180 degrees out of phase.

As to claims 2, 4, 7, 9, 43 and 44, BERRY stent of stainless steel (BERRY, column 8, lines 37-40) has cells formed by the 1<sup>st</sup> to 10<sup>th</sup> members (see Fig. 1 and 5, this paper). Notice that the third loop containing sections/second circumferential bands of BERRY stent is shaped in a sinuous pattern which has a longer longitudinal length in an unexpanded configuration wherein the 5<sup>th</sup> to 10<sup>th</sup> members are closer one to another and a shorter longitudinal length in an expanded configuration wherein the 5<sup>th</sup> to 10<sup>th</sup> members are farther apart one to another. Each cell defines a closed radial opening surrounded by the 1<sup>st</sup> to 10<sup>th</sup> members and each cell will expand in a circumferential direction when the cell is compressed in a longitudinal direction, or each cell will expand in the longitudinal direction when the cell is compressed in the circumferential direction. Therefore, in a straight portion of a curved blood vessel, BERRY stent will provide cells open in length but narrow circumferentially, and in a curved portion of the vessel, some of the cells will be bent and shortened in longitudinal length but widen circumferentially to result in a more constant density of stent element area between the inside and the outside of the curved portion of the vessel or to result in a more constant stent cell area between the inside and the outside of the curved portion of the vessel.

As to claims 11-12, and 14, BERRY (Fig. 1 and 5, this paper) discloses a stent having triangular cells defined by a 1<sup>st</sup> loop-containing section (colored in brown), a 2<sup>nd</sup> loop-containing section (green) and a 3<sup>rd</sup> loop-containing section (purple). The 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> loop-containing sections form a triangular cell (colored in yellow). The 1<sup>st</sup> junction point joins the 1<sup>st</sup> and the 2<sup>nd</sup> loop containing sections, 2<sup>nd</sup> junction point joins the 1<sup>st</sup> and the 3<sup>rd</sup> loop containing sections, and 3<sup>rd</sup> junction point joins the 2<sup>nd</sup> and the 3<sup>rd</sup> loop containing sections as recited in the claims. Notice that the 2<sup>nd</sup> and 3<sup>rd</sup> loop containing sections of BERRY stent are shaped in a sinuous pattern of adjacent struts to define cells (colored in yellow). For the same reason mentioned earlier, in a straight portion of a curved blood vessel, BERRY stent will provide cells open in length but narrow circumferentially, and in a curved portion of the vessel, some of the cells will be bent and shortened in longitudinal length but widen circumferentially to result in a more



constant density of stent element area between the inside and the outside of the curved portion of the vessel or to result in a more constant stent cell area between the inside and the outside of the curved portion of the vessel.

As to claims 16-17, 19, 21-22, and 24, BERRY (Fig. 1 and 5, this paper) discloses vertical (odd and even) meander/first meander patterns (highlighted in red) intertwine horizontal meander/second meander pattern (in green) to form cells (colored in yellow). Notice that the vertical (even) meander/first meander patterns of BERRY stent are shaped in a sinuous pattern of circumferentially adjacent struts which have a longer longitudinal length in an unexpanded configuration where the adjacent struts are closer one to another and a shorter longitudinal length in an expanded configuration where the adjacent struts are farther apart one to another. The meander patterns intertwine and define cells. For the same reason mentioned earlier, in a straight portion of a curved blood vessel, BERRY stent will provide cells open in length but narrow circumferentially, and in a curved portion of the vessel, some of the cells will be bent and shortened in longitudinal length but widen circumferentially to result in a more constant density of stent element area between the inside and the outside of the curved portion of the vessel or to result in a more constant stent cell area between the inside and the outside of the curved portion of the vessel.

As to claims 26-27 and 29, BERRY (Fig. 1 and 5, this paper) discloses stent of stainless steel having 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup>, 6<sup>th</sup>, 7<sup>th</sup>, 8<sup>th</sup>, 9<sup>th</sup>, and 10<sup>th</sup> members which are interconnected as recited in the claims. The curved junction portions of the members define 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> loops as recited in the claims. The 1st to 10th members define a cell. Each cell defines a closed radial opening surrounded by the 1st to 10th members. For the same reason mentioned earlier, in a straight portion of a curved blood vessel, BERRY stent will provide cells open in length but narrow circumferentially, and in a curved portion of the vessel, some of the cells will be bent and shortened in longitudinal length but widen circumferentially to result in a more constant density of stent element area between the inside and the outside of the curved portion of the vessel or to result in a more constant stent cell area between the inside and the outside of the curved portion of the vessel.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 8, 10, 13, 15, 18, 20, 23, 25, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over BERRY et al (6,231,598) as applied to claims 1-2, 4, 6-7, 9, 11-12, 14, 16-17, 19, 21-22, 24, 26-27, 29 above, and further in view of YANG et al (6,120,847).

BERRY discloses substantially all limitations recited in the claims, except for the stent is coated with a medicine for treatment purpose. However, coating a stent with a medicine or drug is well known in the art. For example, YANG discloses a method for coating a therapeutic substance on the surface of the stent for local treatment of a blood vessel. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a medicine coating to BERRY stent so as to have the medicine distributed directly to the treatment site of a blood vessel.

***Election/Restrictions***

Applicant's election with traverse of invention shown in Fig. 3 of the present invention in Paper No. 14 is acknowledged. The traversal is on the ground(s) that (1) all groups of claims are properly presented in the same application; (2) undue diverse searching should not be required; and (3) all claims should be examined together. This is not found persuasive because: (1) the species as identified in the previous "Office Action" clearly show distinct species patentable one over each other; (2) the Applicants

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does not provide any evidence that the species as identified are not distinct inventions;  
(3) claims 31-41 recite limitation(s), for example "square cells", which is mutually exclusive to "triangular cells" shown in Fig. 3, and "square cells" are found only in Figs. 12 or 13 but not in elected species shown in Fig. 3.

The requirement is still deemed proper and is therefore made FINAL.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is (703) 306-1382.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano, can be reached at (703) 308-2496. The fax number for this Unit is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at (703) 308-0858



VQB

September 18, 2002.